Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
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Amendment of Part 95 of the Commission's Rules to Establish a Very Short Distance Two-Way Voice Radio Service	)	WT Docket No. 95-102 RM-8499

To: The Commission

COMMENTS OF
SPACELABS MEDICAL, INC.

SpaceLabs Medical, Inc. ("SpaceLabs"), hereby submits comments in response to the Notice of Proposed Rulemaking ("NPRM"), FCC 95-261, released in the above-captioned proceeding on August 2, 1995.

I. SPACELAB'S INTEREST IN THE PROCEEDING.

Since the late 1960s, SpaceLabs has been designing and manufacturing wireless electrocardiogram ("ECG") monitoring systems, initially using technology developed by the company while working with NASA on then-new biomedical telemetry systems for the manned spaceflight program. At present, there are approximately 200,000 portable ECG transmitters in operation in hospitals and similar healthcare facilities throughout the U.S., approximately one-half of which operate on the 450-470 MHz splinter channels.[1/] Permitting the operation of new unlicensed

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1/ Because of a variety of fairly inflexible power and weight considerations discussed infra, these systems must operate in the band between 100 and 1,000 MHZ. SpaceLabs' early generations of ECG monitors (as well as those of many other manufacturers) primarily operated in the VHF band, under the provisions of Part 15 of the Rules. See generally SpaceLabs, Inc., 26 F.C.C.2d 40 (1970); Laser Systems and

(continued...)

Family Radio Service ("FRS") channels in the 460 MHz band could have a significant impact on the vital medical services presently provided by these telemetry systems.

II. OVERVIEW OF WIRELESS BIOMEDICAL TELEMETRY.

A. System Functions and Capabilities.

An ECG monitoring system records and visually displays the electrical currents that stimulate the contraction of the heart muscle. Irregular heart beats or other cardiac problems are identified by observing distortions in the electrical current represented by the ECG.

In a wireless ECG monitoring system, a small, portable unit (weighing approximately 7 oz.) is carried by the patient in a holster-style arrangement. The portable unit collects data gathered by electrodes attached to the patient's skin and transmits the data to an array of receiving antennas located in the ceiling of the corridors and other common areas of the hospital that are accessible to the patient. The signal is then

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1/ (...continued)
Electronics, Inc., 26 F.C.C.2d 19 (1970). Eventually, the Commission established an exclusive reserve for biomedical telemetry operations under Part 15, on the vacant VHF television channels in the 174-216 MHZ band. See 47 C.F.R. § 15.241; Biomedical Telemetry Radio Systems, 33 F.C.C.2d 880 (1972).

However, because of the severe restrictions on power levels inherent in Part 15 operations (i.e., a maximum field strength of 1500 μV/m measured at 3 m, see 47 C.F.R. § 15.241), some companies (including SpaceLabs) also manufacture ECG monitors that operate on the offset (or "splinter") channels in the 450-470 MHZ band in the Business Radio Service. See 47 C.F.R. §§ 90.75, 90.217, 90.267.

carried via wire to a central point for processing and viewing, generally at a nurse's station. To ensure accuracy, and to aid in identifying potential cardiac problems before they become acute, it is essential that the telemetry system provides a continuous, real-time data stream that is absolutely error-free.

Wireless ECG monitors provide both the hospital and the patient with vastly increased flexibility. Except for circumstances in which the patient is nonambulatory (e.g., in intensive care), it is logistically easier, and far more cost-effective, to employ portable units. More importantly, the portable units permit ambulatory patients a great deal of freedom of movement, an aspect of the recovery process that has become increasingly important in the judgment of the medical profession.

Biomedical telemetry has fairly rigid operational requirements. Communication must be (1) instantaneous, (2) continuous, and (3) free from any interference that might cause a data error. Because of considerations relating to patient safety and battery life, transmissions must be kept to relatively low powers.[2/] Moreover, for reasons of cost, and to ensure proper operation, portable ECG monitors are not frequency-agile; each is tuned to a specific channel. Thus, moving to a new frequency to escape intermittent interference is not just a matter of flipping

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2/ Low power also increases frequency reuse capabilities. In general (depending on variables such as building construction and terrain shielding), frequencies presently may be successfully reused at less than 5,000 foot separations, which is a significant consideration in large urban medical centers.

a switch or turning a dial. Changing frequencies requires that the first monitor be disconnected from the patient and a new one installed. Furthermore, as discussed below, there may not be an alternative channel available to which to move.

The main problem that historically has confronted biomedical telemetry operations is susceptibility to interference, which stems primarily from: (1) its very low operating power; (2) the limited number of channels available in any given locale, particularly in major urban areas where high-power mobile use generally is extensive; and (3) its secondary status vis-à-vis those high-powered systems.

At present, there are approximately 280 splinter channels available for biomedical telemetry.[3/] Because of interference, many of those 280 channels may be unavailable in a particular locale, depending on the nature of co-channel and

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3/ See 47 C.F.R. §§ 90.75, 90.267. The new Part 90 regulatory scheme recently adopted by the Commission in the "spectrum refarming" rulemaking, PR Docket No. 92-235, see Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies Governing Them, FCC 95-255, released June 23, 1995, will impact the number of channels that will be available in the future for low-power biomedical telemetry. While the bandwidth reductions mandated by that decision appear to increase the number of available offset channels by a significant amount (at least over time), the reality of adjacent and co-channel usage patterns may, in practical terms, substantially reduce the intended benefits of "refarming," at least insofar as low-power telemetry is concerned. SpaceLabs has filed a Petition for Reconsideration and/or Clarification ("Petition") of the new Part 90 rules, requesting that the Commission take steps to ensure the availability of an adequate amount of spectrum for use by biomedical telemetry devices on a primary basis.

adjacent channel operations.[4/] In many major medical centers, upwards of 250 telemetry channels may be in operation at any given time, thereby essentially exhausting the available supply in the 450-470 MHz band. If one or more channels are receiving interference from an outside source, there simply may not be an alternative channel available to which to move.

III. THE COMMISSION SHOULD TAKE STEPS TO ENSURE THAT FRS OPERATION DOES NOT INTERFERE WITH BIOMEDICAL TELEMETRY OPERATION.

The introduction of the FRS in the 460 MHz band may significantly impact current biomedical telemetry operations in the 450-470 MHz band by creating unacceptable levels of adjacent channel interference. For example, two of the proposed FRS channels, numbers 7 and 14, are separated by only 50 kHz from current telemetry channels.[5/] Use of these channels by FRS users may cause interference to telemetry units. In some circumstances, there may be unacceptable levels of interference even when the FRS transmitter and the affected telemetry unit are separated by a distance on the order of miles.

[4/] Indeed, seemingly viable splinter channels sometimes turn out to suffer from periods (however brief) of totally debilitating interference, due to the random meanderings of a high-powered mobile unit operating on an adjacent or co-channel.

[5/] While channel 7 is currently licensed under the General Mobile Radio Service, it can reasonably be expected that use of this channel will increase with the introduction of FRS equipment at reasonable prices for unlicensed use. Thus, the potential of interference from FRS channel 7 is likely to increase.

In addition, even if FRS transmitters are not operating on channels adjacent to biomedical telemetry channels, the power level proposed to be authorized for such transmitters (up to 500 mW) would likely exceed a field strength of three volts per meter, the minimum RF susceptibility level for medical devices specified by IEC 801-3. Thus, FRS units may be unacceptable for use in hospitals, particularly in critical care areas.

In view of the above considerations, the Commission should take steps to ensure that the proposed FRS rules do not create an unacceptable interference problem for biomedical telemetry users. In particular, the Commission should rechannel FRS channels 7 and 14, or take other steps to prevent interference with biomedical telemetry equipment operating on adjacent channels.

Furthermore, the Commission should amend the proposed FRS rules to ensure that consumers purchasing FRS units are warned of the dangers of their use in hospitals. This could be accomplished by requiring warnings to placed in user manuals and on the FRS units themselves.

CONCLUSION

As the result of the foregoing, SpaceLabs requests that the Commission craft its rules in such a manner as to minimize the impact of the operation of unlicensed FRS units on low-power biomedical telemetry systems operating in the 450-470 MHZ band.

Respectfully submitted,

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